REMARKS

Claims 1-9, 15-18, 22, 23, 26, 27, 30, 31 are pending.

As seen from this amendment, the plural "s" on the term "Compounds" in claims 2 through 9, 14 through 18, 22 and 23 has been deleted. Even without this plural "s", the claims still and should read on the individual claimed compounds as well as mixtures thereof. Any mixture which contains any of the compounds set forth in these claims will infringe these claims. In accordance with the Examiners suggestion, claim 14 has been canceled. Also the term "or "has been inserted in claim 26 so as to for separate the members of the Markush Group. With regard to claims 1, 3 and 5. "trifluormethoxy" has been corrected so that it now reads -- trifluoromethoxy--. In view of these amendments, claims 1 through 9, 14 through 18, 22, 23 and 26 are no longer subject to a rejection under 35 U.S.C. 112, second paragraph.

Claims 3 and 4 have been amended so that the acyl group reads on a "hydrolyzable acyl radical". This is in accordance with page 5, line 11 through 15 of the instant specification which defines acyl radicals as being a "hydrolyzable radical". These hydrolyzable acyl radicals, in accordance with this invention, do not form the novel part of this invention but are used to protect free amino and hydroxyl groups by forming amides or esters. The use of hydrolyzable acyl protecting groups is not novel and is well known in the art and clearly hydrolyzable acyl radical defines a well known class of radicals used for this purpose. This is sufficient to meet the requirements of 35 U.S.C. 112, first and second paragraph.

The fact that a term such as "acyl define a well known class of radicals known to one skill in the art has been recognized continually in cases by the board and courts which have held that the use of this term in a claim, where they do not define the point

of novelty, is in accordance with the requirements of 35 U.S.C. 112, first and second paragraph. As stated by the Board of Appeals in Ex parte Scherberich, 201 U.S.P.Q. 397, in reversing a rejection of the claims under 35 U.S.C. 112 first and second paragraphs, for using terms such as "aryl" and "aralkyl":

> "As to the term 'aryl, it is recognized that various authorities may place a slightly different interpretation on its meaning; ...we are of the opinion that those in the art readily appreciate the total scope of the subject matter being defined. Irrespective of whether the term 'aryl' is restricted to an 'organic radical derived from an aromatic hydrocarbon by the removal of one atom; e.g., phenyl from benzene, or could be read as inclusive of the tolyl radical...it is believed apparent that the claims' use of the three terms 'aryl', 'aralkyl' and 'aralkyl' clearly indicates the intended scope of the substituent groups'." 201 U.S.P.Q. 397, 399

The term "acyl" like the term aryl as set forth in Ex parte Scherberich, supra, clearly indicates the intended scope of the substituent groups. The novelty of Applicants' invention does not reside in the hydrolyzable acyk radicals since such are known in the art. Therefore, this term meets the requirements of 35 U.S.C. 112. That the term acyl covers a myriad of substituents is not ground for a rejection under 35 U.S.C. 112 Based upon the foregoing, it is submitted that the term "acyl" as used in the claims is in accordance with 35 U.S.C. 112,. first and second paragraph.

In the aforementioned Office Action, In re Kirk et al, 153 USPQ 48 (CCPA 1967) is cited as a basis for holding that the use of broads terms do not satisfy the written description or enablement requirements of 35 U.S.C. 112 The decision of the CCPA in In re Kirk, supra, has nothing to do with any issue concerning the written description or enablement requirements of 35 U.S.C. 112 but rather with the adequacy of the Utility statement in the Kirk application In the Kirk case, the involved application disclosed that the claimed compound was a steroid and it possessed "biological activity In holding

that this was an inadequate disclosure of utility and therefore the application failed to comply with 35 U.S.C. 101 and 112 ,the CCPA ,in the Kirk case ,stated on page 49:

> The Patent Office rejected all the claims for failure of the "specification to comply with 35 U.S.C. 101 and 112". As we review the record, we are concerned with not only the legal adequacy of appellants' disclosure of "how to use" the claim invention under 35 U.S.C. 112 but also the legal adequacy of the assertions of usefulness in the original specification under 35 U.S.C. 101.

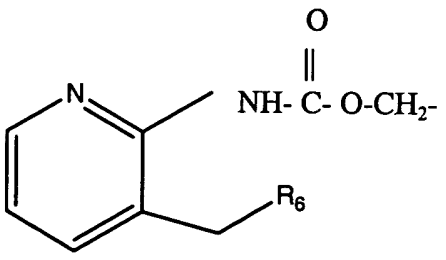
It can not be seen how the Kirk case is applicable to whether the tem aryl defines the substituents to one skilled in the art. There is no rejection on the legal adequacy of the utility disclosure with regard to the instant compounds. In the Kirk case, the CCPA found that "biological activity" did not define any utility to one skilled in the art Certainly, this is not the case in the instant application and the use of the term such as aryl and acyl do define the substitutions encompassed by these terms to one skilled in the art. This is clearly stated in the Ex parte Scherberich and the In re Sus decisions.

All of the claims have been rejected under 35 U.S.C. 102(e) thus being anticipated by Hayase. This rejection is respectfully traversed.

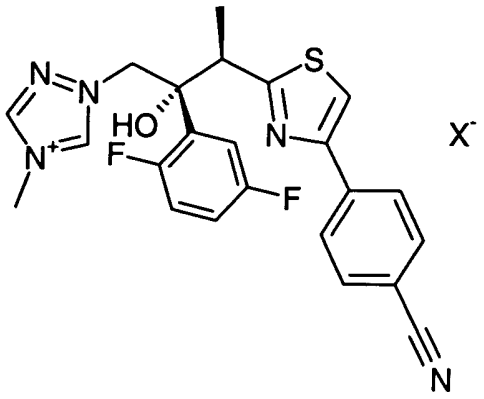
At the outset Applicant wish to point out that the claimed compounds are formed with the following two parts:

A — B

In its simplest terms, Part A consists:



and Part B constitutes



In fact Part A is connected to Part B by a nitrogen in the triazole of Part B

Hayase discloses Part B. However the claimed compound is not Part B. It is Part A connected to Part B by means of a carbamoyloxy linkage via a nitrogen in the triazole of Part B . In order for there to be anticipation, under 35 U.S.C. 102, all of the elements of the claim must be present in the prior art. Without this, a rejection under 35 U.S.C. 102 is not proper. This is clear from the decision of the CCPA in In re Marshal, 198 USPQ 344, which reversed a rejection based on anticipation. In reversing this rejection, the CCPA, at page 346, stated

> Rejections under 35 U.S.C. 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. In re Arkley 59 CCPA 804... 172 USPQ 524, 526 (1972). In other words, to constitute anticipation, all material elements recited in a claim must be found in one unit of the prior art... This basic principal of Patent Law has not been disturbed...

Hayase does not identically disclose or describe the claimed compounds of this invention as required for a 35 U.S.C. 102 anticipation rejection. Since the Hayase reference fails to teach Part A of the claimed compound, it does not set forth all of the elements of the claimed compound. Therefore a rejection under 35 U.S.C. 102 is not proper.

Attention is also direct to In re Meyer, 202 U.S.P.Q. 175, where the CCPA held that even the disclosure of a genus by the prior art does not constitute anticipation under 35 U.S.C. 112, even though the claim species is embodied within the genus. As stated by the CCPA in In re Meyer, 202 USPQ 175 at 179 in holding that the genus does not anticipate the species .

> "For Reissert (the Prior art) to constitute an anticipation, it must identically disclose or describe, inter alia, reacting an alkali metal salt of . . . with an alkali metal hypochlorite. . . . The genus, "alkaline chlorine or bromine solution," does not identically disclose or describe, within the meaning of §102, the species alkali metal hypochlorite. "

Hayase is even more remote than the Reissert reference used in In re Meyers supra, since it does not cover or describe the claimed subject matter, even generically, much less identically as required for a 35 U.S.C. 192 rejection. It is respectfully requested that if this rejection is maintained, that it be pointed out where in Hayase are all of the elements of the claimed invention disclosed.

In order to rely upon Hayase being an anticipation of the claimed invention the Marian Merrell Dow Inc. v. American Cyanamide, 36 USPQ 2nd 1036, is cited This decision has nothing to do with whether a disclosure of Part B by the prior art anticipates the claimed compounds which consists of Part A and B. The question of anticipation is a question of patentability. The issue presented in the Marion Merrell Dow involves an issue of infringement The issue in the Marion Merrell Dow case was whether the importation of a product produced abroad by a process patented in the US infringed the US, the Process Protection Act when the product imported was further processed abroad . The Court in the Marion Merrell Dow case held that in view of the evidence, the further processing of the product abroad was a trivial step and did not

materially change the product produced by the patented process .In view of this the court held that the importation of this further processed product constituted an infringement under the Process Protection Act.

Issues of patentability and infringement are totally different. In fact whether a product which falls under the Process Protection Act so as to infringe a US process patent says nothing about the patentability of that product It is well settled that inventions although embraced within a generic claim of the prior art and which infringed this generic claim can be patentability distinct from the claimed generic invention. See Hester v. Allgeier, 209 USPQ 370 (CCPA 1981). In addition, see the In re Meyer, decision, supra, discussed above, which held that the term alkaline chloride used by the prior art covered the claimed alkaline metal hypochloride, its disclosure did not anticipate or even render obvious the claimed invention Clearly issues of patentability and infringement are two different issues.

Furthermore, in the Merrell case, supra, in order to hold that acetylation step did not materially change the product produced by the claimed process,. the court, on page 1040, relied upon evidence which included various affidavits, various declarations and deposition testimony of three Ph.D's. On the other hand the instant office action provides no evidence for the statement that the precursor and final product are not different products. Without the evidence in the Merrell case, supra, the court could not have reached their conclusion concerning the fact that the step of acetylation did not materially affect the product of the claimed process.

In the Marion Merrell Dow case, supra, evidence was presented that the acetylation step did not materially modify the claimed product of the claimed process. In

the instant situation there is no evidence presented as to whether the modification of Part A to Part B and their attachment via a nitrogen in the triazole of Part B would materially affect the molecule. Without such evidence no rejection under 35 U.S.C. 103, much less 101, can be made. Attention is directed to In re Gordon, 221 USPQ 115 (CAFC 1984) where the rejected claims were directed to the prior apparatus turned upside down. In holding the claimed invention patentable since there was no teaching of turning the apparatus upside down, the CAFC stated:

> "The question is not whether a patentable distinction is created by viewing prior at apparatus from one direction and a claimed apparatus from another, but, rather, whether it would have been obvious from a fair reading of the prior art reference as a whole to turn the prior art apparatus upside down .... The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of such a modification." (221 UPSQ 1125, 1127)

No reason is given as to why the precursor and final product are the same products and the precursor inherently anticipates the final product. As seen from the Umeda declaration, this is not the case.

While Applicants respectfully submit that the above arguments clearly render the present claims neither anticipated nor obvious over Hayase, Applicants have gone further by previously supplying a declaration of Isao Umeda. The Umeda declaration shows that the antigenicity of the N-substituted carbamoyloxyalkyl-azolium derivatives of the present invention is negative while the antigenicity of the corresponding compounds of the Hayase is positive. This declaration presents evidence that demonstrates that the claimed compound consisting of Parts A and B has different properties than the compound of Part B and these properties are new and unexpected.

Hudyama and Davidsen do not disclose the claimed moiety of Part A much less coupling them to the moiety of Part B or coupling them through a nitrogen in the triazole of Part B. In fact Davidson does not disclose either Part A or Part B. While Hudyama discloses Pro- drugs of part B, there is no disclosure of Part A or even coupling the pro drug to part B through a nitrogen in the triazole of Part B There is no suggestion of the modifications of the Part B of the compounds of Hayasse in any of the cited references to give the claimed compounds of this invention. With out such a suggestion there can be no rejection on obviousness as seen from the Gordon case. The suggestion even a simple one of turning the apparatus upside down must come from the prior art and not from the examiner. No evidence has been submitted of any means whereby one could modify the moieties of Part B of Hayase by reaction with Part A to produce the claimed compound of this invention.

Attention is directed to Ex parte Stern, 13 USPQ 1379 (Bd. Pat. App. And Interferences 1987) which required evidence rather than a mere assertion that it would obvious to one skilled in the art to obtain the claimed invention. In Ex parte Stern, supra, the difference between the claimed invention and the prior art was in the degree of purification. In the Stern case, supra, the examiner asserted that the claimed invention was "deemed obvious due to advances in technology which made purification obvious". In holding where there was no means disclosed in the prior art to obtain such a purified compound, the rejection under 35 U.S.C. 103 must fall, the Board in Ex parte Stern, supra, stated:

> The examiner should be aware that 'deeming' does not discharge him from the burden of providing the requisite factual basis and establishing the requisite motivation to support a conclusion of obviousness.... The examiner's

> reference to unidentified phantom prior art techniques falls far short of the mark. (Court's emphasis) 13 USPQ2d at 1381.

No evidence and proof has been provided to support a conclusion that obviousness modifications would result in a compound having the claimed properties. Therefore, the rejection improperly deems applicants' claimed invention obvious. Reliance upon applicants' disclosure and that some of the materials used to formulate the claimed compounds are known cannot be used to provide the requisite evidence of obviousness. There is no teaching in any of the references of any compound embodying the claimed construction of Part A and Part B. and/or that modification of Part B with Part A in the claimed manner would produce a compound having the same or greater activity than the compound of Part B . As stated by the CAFC in In re Vaeck, 20 USPQ2d 1438 at 1440 "both the suggestion and reasonable expectation of success must be found in the prior art, not in applicants' disclosure."

Based upon the foregoing all the claims in this application are in condition for allowance. A prompt notice of allowance is respectfully requested.

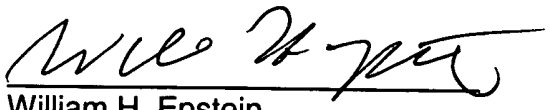
Correspondence and Fees

No fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account no. 03-3839 for any underpayment, or to credit any overpayments.

Please address all correspondence to the correspondent address for **Customer No. 26345 of Intellectual Docket Administrator, Gibbons, Del Deo, Dolan, Griffing r & Vecchi n** , One Riverfront Plaza, Newark, NJ 07102-5497. Telephone

calls should be made to William H. Epstein at (973) 596-4607 or (973) 596-4500 and fax communications should be sent directly to him at 973-639-6397.

Respectfully submitted,



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